IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS INC. ET AL, Plaintiffs, v. SANOFI-AVENTIS U.S. LLC ET AL, Defendants.	2:23-cv-00836-MRH Chief Judge Mark R. Hornak Oral Argument Requested

PLAINTIFFS' RESPONSE IN OPPOSITION TO
DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

From 2001 to 2015, Sanofi held a multi-billion-dollar monopoly over insulin glargine by virtue of a patent protecting its composition. *See* Compl. ¶ 82. That patent expired in 2015, which meant that competitors should have been able to enter the market and increase the availability of lower priced insulin for patients. *See id.* ¶ 93. Instead, Sanofi maintained its monopoly well past the expiration date so it could continue to raise prices, restrict supply, block competition, and accrue billions in profits. It did so through a multi-layered strategy that weaponized the FDA approval process, bought time needed to force the market to adopt a second insulin glargine product, created an exclusionary dual bundle rebating scheme to protect itself from competition while it made the switch to the second product, and punished any customer who tried to make purchases outside of this bundle. These efforts foreclosed Mylan's generic alternative from the market. Patients suffered as a result. The antitrust laws exist to protect consumers and competition from this very avarice, and Sanofi must be held accountable.

In its motion, Sanofi seeks a remedy that the Court cannot provide at this preliminary stage: choose its version of events over Mylan's and decide fact-specific issues in favor of Sanofi. Mylan's non-conclusory allegations, supported with ample evidence from a range of independent third parties, including reports from the U.S. Senate Finance Committee and the U.S. House Committee on Oversight and Government Reform, must be taken as true and sufficiently outline Sanofi's decade-long scheme to thwart generic competition and illegally maintain its monopoly.

STATEMENT OF FACTS

Since its launch in 2001, Sanofi has raked in more than $43.9 billion in net revenue from Lantus, its blockbuster insulin glargine product. *See* Majority Staff Report, Drug Pricing

Investigation, House Committee on Oversight and Reform (Dec. 2021) ("Drug Pricing Rep."),[1] at 28. At first, Sanofi achieved these profits via a patent covering its insulin glargine composition. *See* Compl. ¶ 93. Without competitors, Sanofi could restrict market output and raise prices. The results were staggering: $7.87 billion in gross sales in 2014 *alone*. *See id.* ¶ 94. Millions of Americans resorted to rationing insulin due to exorbitant costs. *See* U.S. Senate Finance Committee, Staff Report, Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug (2021) (hereinafter, "Insulin Rep."), at 14.[2] But, as long as Sanofi's composition patent had not yet expired, insulin glargine was insulated from competition.

Things should have changed in 2015 when Sanofi's patent protecting its insulin glargine composition expired. *See* Compl. ¶¶ 18, 82–85. Generic competitors should have been able to enter the market, increase supply, undercut Sanofi's profit-maximizing prices, and lower prices for patients. *See id.* ¶¶ 18, 80–81. Instead, Sanofi hatched a multifaceted scheme to illegally maintain its monopoly. *See id.* ¶¶ 3–23, 125–26. As detailed in the Complaint, this scheme violated Section 2 of the Sherman Act, Section 3 of the Clayton Act, the New Jersey Antitrust Act, and Pennsylvania common law. *See id*. ¶¶ 232–65. The facts are summarized below.

I. Sanofi Abused The Orange Book and The Hatch-Waxman Act's 30-Month Stay to Delay FDA Approval of Mylan's Generic.

Sanofi continued to monopolize the injectable insulin glargine market by strategically delaying the approval of Mylan's generic[3] alternative ("Semglee™") to Lantus for years. *See* Compl. ¶ 3. To understand how Sanofi accomplished this goal, one must first understand the

[1] The Drug Pricing Report is available at https://oversightdemocrats.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf. *See* Compl. ¶ 8 n.3 (incorporating by reference the Drug Pricing Report).

[2] The Insulin Report is available at https:www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf. *See id.* ¶ 14 n.8 (incorporating by reference the Insulin Report).

[3] During the lifespan of Sanofi's conduct, the nomenclatures associated with regulatory approvals changed, so Mylan's would-be generic received approval as a drug product and was deemed a biologic. For purposes of this brief, we will use the term "generic."

path of bringing generic alternatives to market. *See generally id.* ¶¶ 43–79.

An applicant seeking FDA approval for a new drug under patent protection may identify patents that claim the drug or a use of the drug that could reasonably be asserted in an infringement action. *See* Compl. ¶¶ 47, 57–58. If FDA approves the new drug, it publishes this patent information in a publication referred to as the "Orange Book." *See id.* ¶¶ 46, 49.

A generic manufacturer seeking to enter the market for a branded drug must provide a certification saying either that their product does not infringe patents listed in the Orange Book or that the listed patents are invalid. *See* Compl. ¶¶ 48, 69–74. The provision of this certification grants the brand manufacturer the right to sue for patent infringement. *See id.* Once a brand manufacturer sues a generic manufacturer for patent infringement, FDA generally may not approve the generic manufacturer's drug application until 30 months pass, or until the court finds the patent invalid or not infringed. *See id.* This means the generic drug will be kept off the market for a lengthy period—i.e., a brand manufacturer like Sanofi gets to keep enjoying its monopoly without any competition.

Brand manufacturers (like Sanofi) looking to extend their monopoly can abuse the Orange Book process by listing invalid patents that were not proper for inclusion. The anticompetitive effects can be compounded by creating a "patent thicket." *See* Compl. ¶ 114. This is accomplished by obtaining multiple patents on aspects of the same product, which forces generic manufacturers to fight through the resulting patent thicket to obtain FDA approval. These regulatory and litigation burdens can significantly deter or delay the approval of generic alternatives.

Here, Sanofi used these overlapping strategies to devastating effect. Sanofi listed a panoply of invalid patents that did not meet the Orange Book criteria to trap Mylan in years of

patent litigation and regulatory approval delays. *See* Compl. ¶¶ 4–7, 95–122. Despite initially asserting over a dozen Orange Book patents against Mylan, not one patent claim survived judicial scrutiny. *See id.* ¶¶ 140–90. Of the invalidity challenges to over 50 claims in Sanofi's asserted patents brought through *inter partes* reviews, *only two* claims survived (neither of which could have excluded Mylan), leaving Sanofi with an abysmal success rate of 4%. *See id.* ¶ 143. But outside of the courtroom, Sanofi prevailed anyway. *See id.* ¶ 141. By entangling Mylan's generic product in a patent thicket, Sanofi was able to prolong its injectable insulin glargine monopoly and, in that competition-free environment, lure doctors and patients to its rebranded product, "Toujeo", which did not face generic competition. *See id.* ¶¶ 3, 141–42, 191–94.

II. Building on Its Regulatory and Patent Abuse, Sanofi Next Coerced the Market to Adopt Toujeo and then Tied Toujeo and Lantus to Exclude Generic Competition.

Sanofi further monopolized the insulin glargine market through a multi-layered rebate tying scheme. Sanofi first released Toujeo, a rebranded, therapeutically indistinguishable version of Lantus, at an exorbitantly high price. *See* Compl. ¶¶ 8–12, 195–98. Although this product did not offer any therapeutic advantage over Lantus, Sanofi introduced and marketed Toujeo as a different product, which meant that Mylan's Semglee could not serve as a generic substitute for Toujeo. *See id.* ¶¶ 195, 197, 199–210. Sanofi then tied rebates offered on Lantus to Toujeo's inclusion as an approved drug for insured patients. *See id.* ¶¶ 14, 201–207. This made Mylan's less expensive, therapeutically identical product unattractive to the pharmacy benefit managers ("PBMs") that help choose which drugs are covered by insurance. *See id.* ¶¶ 8–10.

Insurers—including Medicare Part D—rely on these PBMs to negotiate discounts and rebates for drugs offered to their customers. *See* Compl. ¶ 11. Approved drugs are placed on lists called "formularies" that dictate which drugs an insurance plan will cover. *See* Drug Pricing

Rep. at 31; *see also* Insulin Rep. at 34. Pharmaceutical manufacturers may offer rebates and other discounts to obtain favored (and sometimes exclusive) positions on these formularies. *See* Compl. ¶¶ 11–12, 205; Insulin Report at 8.

Here, Sanofi created a powerful combination with Lantus and Toujeo. *See* Compl. ¶ 3. After leveraging its patent thicket against Mylan to impose a 30-month automatic stay under the Hatch-Waxman Act, Sanofi began coercing patients and doctors to Toujeo by tying Lantus rebates (that PBMs were already receiving) with formulary placement of newly introduced Toujeo. *See id.* ¶¶ 11–14. According to the Drug Pricing Report, this meant that PBMs either listed Toujeo on the formulary or forewent *all* Lantus rebates. *See id.* ¶ 203. Sanofi coupled these strong-arm tactics with a marketing blitz, dedicating millions to market Toujeo. *See id.* ¶¶ 207–09. Sanofi's efforts were successful, and by the time of Mylan's Semglee launch, Toujeo held 22.32% of the insulin glargine market. *See id.* ¶ 18.

Once Mylan batted away all of Sanofi's 18 patents, clearing the way for Mylan's Semglee to compete, Sanofi created yet another obstacle, conditioning Toujeo rebates on maintaining Lantus on formulary at a preferred or exclusive position relative to Semglee. *See* Compl. ¶¶ 6, 204, 209. In so doing, Sanofi leveraged the demand it purposefully manufactured for Toujeo to tie Toujeo and Lantus rebates together and coerce PBMs to exclude Semglee from formularies. *See id.* ¶¶ 3, 210.

This multi-layered scheme prevented Mylan's Semglee product from obtaining any measurable sales until more than a year after it was finally able to enter the market. *See* Compl. ¶ 211. By splitting insulin glargine across two different products, one with established demand (Lantus) and one with patent protection (Toujeo), Sanofi transformed PBMs into a cudgel that substantially foreclosed Mylan. Because Mylan did not have a Toujeo generic, PBMs had no

choice but to place Lantus and Toujeo on preferred or exclusive formulary tiers in order to satisfy the demand Sanofi spent millions to manufacture. *See id.* ¶¶ 201–209. Moreover, tying the Toujeo and Lantus rebates in a dual product bundle made it impossible for Mylan, as a single-product competitor, to compete as a less expensive generic. *See id.* ¶ 13.

ARGUMENT

Throughout its brief, Sanofi mischaracterizes Mylan's claims. Mylan does not allege that Sanofi committed a discrete series of separate anticompetitive acts—improper listing of invalid patents in the Orange Book, sham patent litigation, introducing a product to avoid forthcoming generic entry, and dual product bundling—each with a compartmentalized effect on competition. Rather, Mylan alleges that Sanofi orchestrated a comprehensive plan to maintain a 20-year+ monopoly on injectable insulin glargine beyond its lawful lifespan, and accomplished this plan in phases through interconnected anticompetitive acts. *See* Drug Pricing Rep. at iv. These continuing violations of federal and state antitrust laws reinforced each other for almost a decade, and the scheme was only fully revealed when Congress stepped in to investigate why so many people were unable to afford this drug. *See* Drug Pricing Rep. at 114–15. Antitrust law is fact-bound and turns on "actual market realities," not "formalistic distinctions." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 466–467 (1992). Mylan's Complaint provides the "actual market realities" created and perpetuated by Sanofi's illegal conduct. Sanofi's invitation to ignore Mylan's allegations in favor of Sanofi's version of formalistic distinctions is contrary to the law. *See id.*

"The court must take the complaint's [non-conclusory] factual allegations as true," *Martinez v. UPMC Susquehanna*, 986 F.3d 261, 265 (3d Cir. 2021), and must construe the complaint "in the light most favorable to the plaintiff," *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 314 (3d Cir. 2010). A complaint need only contain "enough facts to state a claim to

relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). But the plausibility standard does not amount to "a probability requirement." *Id*. at 556. Instead, it "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of the necessary element." *W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010) (internal quotations omitted). Thus, even in "antitrust and other complex cases," the plausibility standard carries no "extra bite." *Id*. Indeed, dismissals in antitrust cases "prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly." *Premier Comp Sols. LLC v. UPMC*, 163 F. Supp. 3d 268, 275 (W.D. Pa. 2016).

Under the correct legal standard, the only question is whether Mylan's monopolization and related claims are plausible. They are. Sanofi's motion must thus be denied.

I. Mylan Has Alleged a Plausible Monopolization Claim.

A monopolization claim has two elements: "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power." *In re Lipitor Antitrust Litig.*, 855 F.3d 126, 147 (3d Cir. 2017). "But to be condemned as exclusionary, a monopolist's anticompetitive conduct must have an anticompetitive effect," which must be caused by the "monopolist's conduct taken as a whole rather than considering each aspect in isolation." *Id.* (quoting *LePage's Inc. v. 3M*, 324 F.3d 141, 146 (3d Cir. 2003) (en banc)). Mylan's allegations viewed individually, and taken as a whole, plausibly allege monopolization.

A. Sanofi Willfully Acquired and Maintained Monopoly Power.

A monopolization claim "requires the willful acquisition or maintenance of monopoly power." *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007). This willfulness requirement must involve anticompetitive conduct. *Id*. For example, blocking the opportunities of rivals without competing on the merits or in an "unnecessarily restrictive way" may be considered "anticompetitive" conduct. *Id.*

1. Mylan alleged an overall, anticompetitive scheme, not a series of discrete, unconnected, anticompetitive acts.

Sanofi's motion would have the Court believe that Mylan aimlessly alleged a series of discrete, anticompetitive acts bearing no relationship to one another. *See* D.I. 50 at 1. Not so. Mylan clearly alleged that Sanofi engaged in three broad, intertwined, anticompetitive acts collectively designed to extend its monopoly power and to block Mylan from entering the market: (1) the improper Orange Book listings and attendant sham patent litigation; (2) the introduction of Toujeo and manipulation of the market to avoid generic substitution; and (3) the tying of Toujeo rebates to Lantus's preferred formulary placement at the exclusion of Mylan's Semglee. *See* Compl. ¶¶ 3–23. Each of these acts was designed to reinforce the other and cause Mylan—and patients—anticompetitive injury. Mylan properly alleged this overall anticompetitive scheme. Sanofi might prefer to disaggregate individual components of that whole and attack each as alone insufficient (which they are not), but the law expressly prohibits this wholesale restructuring of Mylan's monopolization claim on a motion to dismiss.

Anticompetitive conduct occurs whenever companies attempt to exclude rivals "on some basis other than the merits." *W. Penn Allegheny Health Sys.*, 627 F.3d at 108 (quoting *LePage's*, 324 F.3d at 147). The means of exclusion can vary widely from case to case. *See, e.g.*, *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 622 F. Supp. 3d 22, 59–60 (E.D. Pa. 2022) (hereinafter, "*Suboxone*") (noting anticompetitive conduct "can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties") (citations omitted). The challenged conduct must be scrutinized as a whole "without tightly compartmentalizing the various factual components and wiping the slate clean after scrutiny of each." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962).

One type of monopolization conduct is a continuing, multifaceted anticompetitive scheme. When considering such a scheme, "[t]he relevant inquiry is the anticompetitive effect of [the defendant]'s exclusionary practices considered together." *LePage's*, 324 F.3d at 162. And "the Third Circuit has explicitly recognized that independently lawful conduct—*i.e.*, discount programs, rebates, exclusive dealing contracts—can have an anticompetitive effect that is actionable under antitrust law" when part of a broader course of anticompetitive conduct. *Suboxone*, 622 F. Supp. 3d at 61 (citing *LePage's*, 324 F.3d at 158–59); *see also, e.g.*, *Suboxone*, 967 F.3d 264, 270 (3d Cir. 2020); *Phila. Taxi Ass'n, Inc. v. Uber Techs., Inc.*, 886 F.3d 332, 339 (3d Cir. 2018); *Indivior Inc. v. Alvogen Pine Brook LLC*, 2023 WL 6936749, at *15 n.23 (D.N.J. July 10, 2023).[4]

Accordingly, the question is whether the conduct described in Mylan's Complaint, taken as a whole, plausibly alleges anticompetitive conduct. As outlined below, it does.

2. Mylan's claims based on listing invalid patents and sham litigation are not time-barred.

Sanofi argues that Mylan's claims based on listing invalid patents in the Orange Book and sham litigation are barred by the four-year statute of limitations. D.I. 50 at 21–22. But these events cannot be viewed in a vacuum. Indeed, a monopolization scheme is a "continuing violation," *Hanover Shoe v. United Shoe Mach. Corp.*, 392 U.S. 481, 502 n.15 (1968), making the relevant consideration the "cumulative effect of individual acts." *Nat'l R.R. Passenger Corp. v. Morgan*, 536 U.S. 101, 115 (2002). Taken together, Sanofi's continuing anticompetitive

[4] Sanofi says the Supreme Court rejected this style of monopolization claim in *Pacific Bell Telephone Co. v. linkLine Communications, Inc.*, 555 U.S. 438 (2009). Sanofi is wrong. Numerous courts have explained that *linkLine*'s holding is confined to "price squeezes" and did not reject overall scheme claims. *See, e.g.*, *FTC v. Qualcomm, Inc.*, 2017 WL 2774406, at *18 (N.D. Cal. June 26, 2017) ("*linkLine* did not address allegations of an 'overarching anticompetitive scheme'"); *accord In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at *15 (D.N.J. Aug. 28, 2009). And the Third Circuit has continued to recognize multifaceted monopolization schemes since *linkLine*. *See, e.g.*, *Suboxone*, 967 F.3d at 270; *Phila. Taxi Ass'n*, 886 F.3d at 339.

conduct harmed Mylan far beyond the statute of limitations in Mylan's causes of action.[5] *See Brenner v. Loc. 514, United Bhd. of Carpenters & Joiners of Am.*, 927 F.2d 1283, 1295 (3d Cir. 1991) (discussing continuing violation doctrine). The proper inquiry focuses on whether affirmative acts were taken as part of a pattern of wrongdoing. *See id.* at 1296. As discussed *supra* at 1–46, Sanofi's years-long practice constituted a series of affirmative acts that wrongfully precluded Mylan from entering the market.[6] *See Brenner*, 927 F.2d at 1295.

Sanofi's monopolistic conduct prevented Mylan from bringing Semglee to market for over five years, with harm continuing into the sixth and seventh years. *See* Compl. ¶¶ 15–16, 123, 209–11, 231. Each one of those years was an integral part of Sanofi's continued scheme to prevent competition and solidify its illegal market position.

Sanofi's Lantus lost patent exclusivity on February 13, 2015. Compl. ¶ 85. From that date forward, in a competitive system, Mylan should have been able to meaningfully compete with Lantus and Toujeo. But Mylan could not. With improper listings in the Orange Book and sham litigation (*see, e.g.*, *id.* ¶¶ 3–6, 140–90), and with dual rebate tying schemes and exclusive dealing (*see, e.g., id.* ¶¶ 8, 11, 14, 195–211), Sanofi successfully blocked Mylan's access to the market.

The timing of when Mylan ascertained the extent of its damages cannot be resolved on a motion to dismiss. *See Suboxone*, 2017 WL 4910673, at *18 (E.D. Pa. Oct. 30, 2017). To prevail on a statute of limitations defense, a plaintiff's untimeliness in initiating the action "must be apparent from the face of the complaint." *W. Penn Allegheny Health Sys.*, 627 F.3d at 105

[5] The Sherman, Clayton, and New Jersey Antitrust Act have a four-year limitations period, and Mylan's claim of tortious inducement of refusal to deal has a two-year limitations period. *See* 15 U.S.C. § 15b; N.J. Stat. § 56:9-14.

[6] Sanofi does not contest that Mylan's claims concerning Sanofi's product-hopping and bundling components of the overall scheme are within the statute of limitations. *Cf.* D.I. 50 at 21–22. As a result, Sanofi has forfeited any arguments to the contrary. *See Laborers' Int'l Union v. Foster Wheeler Corp.*, 26 F.3d 375,398 (3d Cir. 1994).

n.13. Here, it is not. The Complaint makes clear that Mylan did not have full visibility into Sanofi's monopolization scheme until at least 2021, when the Senate Finance Committee's Insulin Report and the Committee on Oversight and Reform's Drug Pricing Report were released. *See* Compl. ¶¶ 8, 11, 203. These reports revealed facts that Mylan did not know and could not have known. These include Sanofi's internal plans to strategically move the market to Toujeo ahead of Mylan's Semglee launch while Mylan was delayed and battling its way through Sanofi's serial petitions, and rebate-tying contracts to exclude Mylan's generic from formularies. *See id.* ¶¶ 203–04. Indeed, "it is hornbook law, in antitrust actions as in others, that even if injury and a cause of action have accrued as of a certain date, future damages that might arise from the conduct sued on are unrecoverable if the fact of their accrual is speculative ***or their amount and nature unprovable***." *Meijer, Inc. v. 3M*, 2005 WL 1660188, at *5 (E.D. Pa. July 13, 2005) (citation omitted) (emphasis added). Whether the amount and full nature of Mylan's harm was knowable before 2021 cannot be resolved at this stage. *See Suboxone*, 2017 WL 4910673, at *18. Further, Sanofi's fraudulent concealment of its monopolistic scheme—and Mylan's inability to discover Sanofi's scheme until the 2021 Reports—tolled the statute of limitations. *See In re Elec. Carbon Prods. Antitrust Litig.*, 333 F. Supp. 2d 303, 315–17 (D.N.J. 2004); *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 160, 163 (3d Cir. 2002); *Bethlehem Steel Corp. v. Fischbach & Moore, Inc.*, 641 F. Supp. 271, 272, 275 (E.D. Pa. 1986).

3. Sanofi's sham patent litigation is not immune from antitrust scrutiny.

Sanofi invokes *Noerr-Pennington* immunity and asserts that the sham litigation exception to that doctrine does not apply because Mylan's Complaint does not allege how Sanofi's patent litigation against Mylan was objectively baseless. *See* D.I. 50 at 22–23. But that is not the test. Sanofi ignores the fact—set forth repeatedly in Mylan's Complaint (¶¶ 141, 142, 192)—that this case concerns a pattern of *serial* petitioning. Because of this misconstruction, Sanofi's motion

dwells on the wrong prong. It focuses on arguing—incorrectly—why its patent cases against Mylan were not objectively baseless and entirely fails to address the subjective prong.

Ordinarily, a lawsuit loses its *Noerr-Pennington* immunity if it is both objectively baseless and subjectively motivated by anticompetitive intent. *Pro. Real Estate Invs, Inc. v. Columbia Pictures Indus, Inc.*, 508 U.S. 49, 60–61 (1993) ("*PRE*"); *see also Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 179 (3d Cir. 2015). But *serial* petitions are evaluated under the more lenient test from *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 513 (1972).

Under this test, a conclusion that one or more of a defendant's petitions were meritorious does not automatically preclude a finding that the sham exception applies, and the defendant's subjective motivation must be considered. *See Hanover 3201 Realty*, 806 F.3d at 180. The rationale for this rule is that filing multiple petitions increases the chances that one or more of them will be successful, and therefore not objectively baseless. *Id.* (citing *USS–POSCO Indus. v. Contra Costa Cnty. Bldg. & Constr. Trades Council, AFL–CIO*, 31 F.3d 800, 811 (9th Cir. 1994) ("[E]ven a broken clock is right twice a day.")). As a result, when a plaintiff alleges a series of legal proceedings, the defendant cannot defeat a sham petition allegation if some of the petitions turn out to have some objective merit; rather, the proper inquiry asks "whether a series of petitions were filed with or without regard to merit and for the purpose of using the governmental process (as opposed to the outcome of that process) to harm a market rival and restrain trade." *Hanover 3201 Realty*, 806 F.3d at 180. "In deciding whether there was such a policy of filing petitions with or without regard to merit, a court should perform a holistic review that may include looking at the defendant's filing success—i.e., win-loss percentage—as circumstantial evidence of the defendant's subjective motivations." *Id.*

In *Kearns v. Gen. Motors Corp.*, 94 F.3d 1553, 1555 (Fed. Cir. 1996), the Federal Circuit recognized that "[e]ach patent asserted raises an independent and distinct cause of action." Sanofi asserted *18* such causes of action against Mylan. *See* Compl. ¶ 145. Sanofi lost again and again (or chose to drop some patents only after receiving the benefit of the attendant 30-month stay). Sanofi could not prove infringement as to a single valid patent. *See id.* ¶¶ 146–90. And of the challenges to over 50 claims in Sanofi's asserted patents brought through *inter partes* reviews, *only two* claims survived (neither of which could have excluded Mylan's product because it did not infringe, as evidenced by Sanofi granting a covenant not to sue), leaving Sanofi with an invalidity success rate of 4%. *Id.* at ¶ 143.

The serial petitioning rule applies here. Although Sanofi initiated only one lawsuit against Mylan, that suit included 18 claims of patent infringement. Compl. ¶ 145. The rationale for applying *California Motors* is the insight that more at-bats mean more chances of "hitting a single in the second inning." *Hanover 3201 Realty*, 806 F.3d at 182. It does not matter whether those additional at-bats occur simultaneously in one voluminous lawsuit or sequentially in multiple lawsuits.[7] Requiring a literal series of lawsuits places form over substance.[8] And, in any event, Sanofi continued to advance its validity arguments in separate *inter partes* review proceedings before the Federal Circuit for several patents. *See, e.g.*, Compl. ¶¶ 5, 143.

Finally, "district courts within this Circuit have routinely prohibited parties from

[7] Indeed, in *California Motor*, the Court stated that it was "a pattern of baseless, repetitive claims," not lawsuits, that could "lead[] the factfinder to conclude that the administrative and judicial processes have been abused." 404 U.S. at 513. *See also Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 414 (3d Cir. 2016) (assuming that "a single claim, separated from an otherwise arguably meritorious suit," could be "so harmful and costly to a defendant that it might impose anticompetitive harm on the defendant in a way that triggers the sham litigation exception to *Noerr–Pennington*.").

[8] *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132 (3d Cir. 2017) is not to the contrary. While the Third Circuit held there that two lawsuits did not amount to a series of petitions, *id.* at 157, both lawsuits at issue asserted only two patent infringement claims apiece. Complaint, *Meijer, Inc. v. Biovail Corp.*, No. 2:08-cv-2431 (E.D. Pa. May 23, 2008), ECF No. 1, at 21–22. That is far fewer than the 18 patents Sanofi asserted here.

invoking the protections of *Noerr-Pennington* at the dismissal stage of a case." *Takeda Pharm. Co. v. Zydus Pharms. (USA) Inc.*, 358 F. Supp. 3d 389, 394–95 (D.N.J. 2018) (collecting cases). While a court *may* apply *Noerr-Pennington* on a motion to dismiss, "the issue is a fact-intensive one, generally not suitable for resolution at the pleading stage." *Indivior v. Dr. Reddy's Lab'ys S.A.*, 2020 WL 4932547, at *8 (D.N.J. Aug. 24, 2020).[9] Instead, whether litigation is a sham "is generally a question of fact for the jury" unsuitable for resolution on a motion to dismiss. *Indep. Taxicab Drivers' Emps. v. Greater Hous. Transp. Co.*, 760 F.2d 607, 612 n.9 (5th Cir. 1985). That is particularly true here where the issue turns on Sanofi's subjective intent, because "[m]otive is a question of fact that must be decided by the jury, which has the opportunity to hear the explanations of both parties in the courtroom and observe their demeanor." *Monteiro v. City of Elizabeth*, 436 F.3d 397, 405 (3d Cir. 2006).

4. Sanofi's exclusionary formulary practices excluded Mylan's generic product from the market once finally approved.

When addressing a claim that "a rival's sales program violates the antitrust laws, [the court] must consider whether the conduct constitutes an exclusive dealing arrangement or simply a pricing practice." *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 408 (3d Cir. 2016). Sanofi's attack on Mylan's exclusive dealing allegations elides this threshold distinction, leading it to assert defenses relevant to pricing practices but irrelevant here (among other errors). In particular, Sanofi overlooks how exclusive dealing arrangements may be "effectuat[ed]" by "bundled rebates." *LePage's Inc. v. 3M*, 324 F.3d at 154 (3d Cir. 2003) (en banc); *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 282 (3d Cir. 2012) (recognizing that "bundled rebates [can]

[9] *See also S3 Graphics Co. v. ATI Techs. ULC*, 2014 WL 573358, at *3 (D. Del. Feb. 11, 2014) (resolution of *Noerr-Pennington* immunity "not proper before discovery"); *In re JUUL Labs, Inc. Mktg, Sales Pracs. & Prods. Liab. Litig.*, 2022 WL 1601418, at *19 (N.D. Cal. Apr. 29, 2022) (*Noerr-Pennington* issue "is better determined after the evidence comes in at trial and on post-trial motions").

operate as exclusive dealing arrangements, despite the lack of express exclusivity requirements").[10]

a. Sanofi's rebating practices function as an illegal tie.

One way to "break the competitive mechanism," *ZF Meritor*, 696 F.3d at 285, is by tying different products together for the purpose of bundling rebates across products, foreclosing the market to a competitor who does not "manufacture an equally diverse group of products and who therefore cannot make a comparable offer," *LePage's*, 324 F.3d at 155.[11] Bundling rebates is anticompetitive because it induces "buyers to take increasing amounts or even all of a product in order to take advantage of a discount aggregated across multiple products." *Id.* (quoting Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 794, at 83 (Supp. 2002)).[12] By packaging discounts, "the defendant rewards the customer for buying its product B rather than the plaintiff's B, not because defendant's B is better or even cheaper," *id.*, making rebate bundles a form of competition on "some basis other

[10] Sanofi criticizes Mylan for not "alleging the existence of a specific exclusivity agreement." D.I. 50 at 8. But Mylan does not need to plead an express exclusivity clause in Sanofi's PBM contracts, because Mylan does not have to prove such a clause exists. Express exclusivity requirements are not necessary because courts "look past the terms of the contract to ascertain the relationship between the parties and the effect of the agreement 'in the real world.'" *ZF Meritor*, 696 F.3d at 270. Thus, *de facto* exclusive arrangements may be challenged under the antitrust laws. *See Eisai*, 821 F.3d at 403. Here, Sanofi's internal documents, incorporated into the Complaint, demonstrate that, in the real world, tying Lantus and Toujeo together gave Sanofi preferred access and allowed Sanofi to maintain Lantus as the "preferred 1st generation basal insulin." Compl. ¶ 10.

[11] "Bundling is the practice of offering, for a single price, two or more goods or services that could be sold separately." *Eisai*, 821 F.3d at 405 n.32 (quoting *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 894 (9th Cir. 2008)).

[12] The Courts of Appeals disagree as to what makes bundling anticompetitive. Some Circuits consider bundling a form of pricing and will only hold it unlawful if it is predatory, *i.e.*, when the combined discounts applied to a single product in the bundle would render that product priced below cost. *See, e.g.*, *Cascade Health*, 515 F.3d at 902 (applying price-cost test from *Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993)). The Third Circuit differs. It analogizes bundling of discounts to the unlawful practice of tying, the practice whereby a party offers "to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier." *Eisai*, 821 F.3d at 405 & n.34 (quoting *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. at 461–62 (1992)). Importantly, the exclusionary nature of tying does not involve below-cost pricing. *ZF Meritor*, 696 F.3d at 278–79. The Third Circuit's bundling test is regarded as less strict and more easily satisfied by plaintiffs. *See Regeneron Pharms., Inc. v. Amgen Inc.*, 2023 WL 1927544, at *6 (D. Del. Feb. 10, 2023), *R&R adopted*, 2023 WL 2587809 (D. Del. Mar. 21, 2023).

than the merits," *LePage's*, 324 F.3d at 147. When "the customer buys the defendant's B in order to receive a greater discount on A, which the plaintiff does not produce," bundling becomes coercive because it punishes disloyal customers. *Id.* Sanofi threatened to punish customers for choosing Semglee over Lantus with not only the loss of a rebate on Lantus but on Toujeo too. Compl. ¶¶ 204, 247.

Sanofi's Lantus-Toujeo bundle was coercive. Despite entering the market at a significantly lower price, Mylan could not make any headway until 2021. There are numerous strategies Sanofi could have deployed to coerce customers into excluding a less expensive product from the formulary—strategies discovery will no doubt reveal. But, at this early stage, Mylan plausibly alleges that its less expensive product could not enter the market because of Sanofi's coercive practices, and that is sufficient to survive a motion to dismiss. *See Castro v. Sanofi Pasteur Inc.*, 2012 WL 12516572, at *9–10 (D.N.J. Aug. 6, 2012) (another challenge to Sanofi's bundled rebates); *3Shape Trios A/S v. Align Tech., Inc.*, 2020 WL 2559777, at *8 (D. Del. May 20, 2020), *R&R adopted*, 2020 WL 6938054 (D. Del. Nov. 25, 2020).

Sanofi insists that its formulary practices can only be found anticompetitive if they fail the price-cost test. *See* D.I. 50 at 6–7. But the price-cost test only applies where a defendant's pricing "is the clearly predominant mechanism of exclusion." *ZF Meritor*, 696 F.3d at 269. Mylan alleges that an exclusivity condition in a contract—not a price—excludes its product, and that Sanofi used bundled rebates, in essence a tie—not a price—to strong-arm customers into accepting that exclusivity term. Thus, the price-cost test is "inapposite," and the rule of reason applies instead. *Suboxone*, 622 F. Supp. 3d at 65–66.[13] "Nothing in the case law suggests, nor

[13] *See also, e.g.*, *UniStrip Techs., LLC v. LifeScan, Inc.*, 153 F. Supp. 3d 728, 736–37 (E.D. Pa. 2015) (price-cost test does not apply to exclusive dealing claim where plaintiff never alleged that price was the means of exclusion); *In re Surescripts Antitrust Litig.*, 608 F. Supp. 3d 629, 642 (N.D. Ill. 2022) (Because Plaintiffs

(*continued on the next page*)

would it be sound policy to hold, that above-cost prices render an otherwise unlawful exclusive dealing agreement lawful." *ZF Meritor*, 696 F.3d at 278.

Sanofi's rebate payments do not change that result. The presence of payments is not a talisman that converts any case into a predatory-pricing suit. Payments in the form of bundled discounts may be used by "a dominant supplier" to secure "*de facto* exclusive dealing arrangements." *ZF Meritor*, 696 F.3d at 281. When that is so, the harm is caused "not by the price [but] rather by the condition limiting rivals' sales." Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶ 768b4 (2023) (hereinafter "Areeda & Hovenkamp"). "In these [cases], simply querying whether the fully discounted price is above cost often misses important elements of exclusion." *Id.* And thus, when a brand's practices are challenged on bundling and exclusive-dealing grounds, they may be held illegal "irrespective of below-cost pricing." *ZF Meritor*, 696 F.3d at 281.

Sanofi posits, wrongly, that *Mylan* alleges that Lantus and Toujeo are the same product. *See* D.I. 50 at 5–6. Sanofi then attacks that straw man by arguing that tying Lantus and Toujeo together is therefore not anticompetitive. *See id.* Mylan alleges that Lantus and Toujeo are therapeutically indistinguishable. *See* Compl. ¶¶ 8, 195–97. That is a far cry from alleging that Lantus and Toujeo are the same *products*. They are certainly different products where it counts for purposes of competition—namely, at the pharmacy counter. *See id.* ¶ 81. A prescription for Lantus cannot be filled with Toujeo, nor vice versa, as the drugs contain different levels of insulin glargine. *See id.* ¶ 195.

Moreover, through its own conduct, Sanofi made clear that Lantus and Toujeo should be treated by PBMs as two separate products. Were these not separate products, Sanofi's decision

"[n]owhere . . . allege that [Defendants'] prices are now, or ever were, too low," the "predatory pricing rubric is . . . inappropriate here.").

to sell them under two separate brand names would make no sense, particularly given the expense and effort required for creating and promoting a new brand name. *See* Compl. ¶ 207. The "commercial realities" of the pharmaceutical industry only reinforce that Lantus and Toujeo are different products. *Eastman*, 504 U.S. at 482 (1992); *Lifewatch Servs. Inc. v. Highmark Inc.*, 902 F.3d 323, 337 (3d Cir. 2018).

Sanofi also argues that its use of bundled rebates to secure exclusive positions on state Medicaid formularies are immune from antitrust scrutiny from *Noerr-Pennington*. *See* D.I. 50 at 7. But *Noerr* deals with petitions to the government to make a choice, not efforts to coerce the government. *See* Areeda & Hovenkamp ¶ 209a; *see also Sacramento Coca-Cola Bottling Co. v. Chauffeurs, Teamsters & Helpers Local No. 150*, 440 F.2d 1096, 1099 (9th Cir. 1971) (*Noerr* immunity does not apply to "coercive measures"). Sanofi's bundled rebates constrained the free exercise of choice by private and government payers alike. And there is no *Noerr* immunity where the government is "forced to purchase the defendant's bundle." Areeda & Hovenkamp ¶ 209b; *see also Suboxone*, 622 F. Supp. 3d at 76–77 (concluding *Noerr* did not apply to anticompetitive scheme involving Medicaid).[14]

Sanofi's argument that Mylan can offer a competing bundle based on its diverse catalogue of drugs is both wrong and perverse from a competitive standpoint. *See* D.I. 50 at 7–8. First, when Mylan launched, it offered a single insulin glargine product: Semglee. *See* Compl. ¶ 139. It is nonsensical to interpret *ZF Meritor*'s statement that "*LePage*'*s* is limited to cases in

[14] *EpiPen* is not to the contrary. There, the court held *Noerr* immunized Mylan's efforts to secure favorable positions on state Medicaid formularies. *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 2017 WL 6524839, at *10–11 (D. Kan. Dec. 21, 2017). The difference is *EpiPen* concerned the use of a "single-product loyalty discount or rebate," *In re EpiPen*, 44. F.4th 959, 983 n.7 (10th Cir. 2022), which the Third Circuit considers a pricing practice subject to the price-cost test, *id.* (quoting *Eisai*, 821 F.3d at 409 (3d Cir. 2016)), and not a coercive tying arrangement like *bundled* rebates, *see Eisai*, 821 F.3d at 405. In the absence of coercion, Mylan's offers to state Medicaid agencies in *EpiPen* "amount[ed] to nothing more than lobbying of government officials"—the very conduct *Noerr* shields. *In re EpiPen*, 2017 WL 6524839, at *11 (quotation omitted).

which a single-product producer is excluded through a bundled rebate program" (696 F.3d at 274 n.11) to refer to competitors that *literally* offer only a single product.[15] As *ZF Meritor* explained, the reason LePage's could not compete with 3M was not because it only sold one product, but because "it did not sell *the same* diverse array of products as 3M." *Id.* (emphasis added); *see also Eisai*, 821 F.3d at 404. Second, Sanofi's proposed solution is a race to the bottom that would require Mylan, and others, to also engage in coercive contracting practices. But the solution to anticompetitive behavior is not more anticompetitive behavior. *See United States v. Apple Inc.*, 952 F. Supp. 2d 638, 708 (S.D.N.Y. 2013) ("Another company's alleged violation of antitrust laws is not an excuse for engaging in your own violations of law."), *aff'd*, 791 F.3d 290 (2d Cir. 2015).

At bottom, Mylan alleges that Sanofi created demand for Toujeo, released a therapeutically indistinguishable but nonetheless *different* product not facing generic competition to satisfy that demand, and then tied rebates between both Lantus and Toujeo to preserve its monopoly over the injectable insulin glargine market. *See* Compl. ¶¶ 195–211. Put differently, Sanofi found a way to manufacture a new market for the same drug and compete with Mylan on terms other than the merits, raising prices for patients and harming competition. That this anticompetitive conduct collectively includes components of bundling, tying, and product-hopping is no basis for dismissal. *See Suboxone*, 622 F. Supp. 3d at 59–60.

[15] To begin, *LePage's* itself sold more than one product. *See* Second Am. Compl. ¶ 1, *LePage's Inc. v. 3M*, No. 97-cv-3983 (E.D. Pa. Sept. 2, 1998), D.I. 93, at 2 ("LePage's manufactures home and office products, with its principal product being invisible and transparent home and office tape. In 1995, more than 80% of LePage's total sales consisted of tape sales."). So to interpret *ZF Meritor* to limit *LePage's* to instances where the plaintiff sells only a single product would be to effectively overrule *LePage's*, which the *ZF Meritor* panel could not do. *See In re Aleckna*, 13 F.4th 337, 344 n.38 (3d Cir. 2021) (precedential panel decisions are binding on future panels and can only be overturned by en banc court). For its part, the FTC agrees that the proper analysis compares the defendant's bundle and the plaintiff's competing products, not the plaintiff's entire portfolio. *See* Amicus Br. on Behalf of the FTC at 13, *Applied Med. Resources Corp. v. Medtronic, Inc.*, No. 8:23-cv-268 (C.D. Cal. July 3, 2023), D.I. 27–1 at 19 ("[Bundling] is most concerning when a dominant firm sells a full bundle, while a smaller firm sells only some *products* in that bundle.") (emphasis added).

b. Sanofi's product hop is not dependent on a "hard switch."

Finally, Sanofi argues that Mylan's monopolization claims must fail because it did not allege a "hard switch" from Lantus to Toujeo. D.I. 50 at 9 (citing cases where the alleged monopolist removed the earlier product from the market). But a hard switch is not necessary for a product hop to be anticompetitive. What is required is some form of coercion that constrains the free choice of consumers, and "withdrawal of an old product is not the only means of coercion." *In re HIV Antitrust Litig.*, 2023 WL 3088218, at *8 (N.D. Cal. Feb. 17, 2023); *see also In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 330 (D.R.I. 2019) ("This argument [that no hard switch may occur where the prior product is not withdrawn] is easily snuffed out by the law.").[16] Here, Sanofi coerced purchasers through the bundling of rebates. The cases Sanofi cites are distinguishable because they did not involve similarly coercive practices.

B. Sanofi Has Monopoly Power in The Relevant Market.

Mylan alleges that at all relevant times, Sanofi had monopoly power in the market for injectable insulin glargine. *See* Compl. ¶ 212. Monopoly power is the ability to control prices and exclude competition in a given market. *Broadcom*, 501 F.3d at 307. "If a firm can profitably raise prices without causing competing firms to expand output and drive down prices, that firm has monopoly power." *Id.* Thus, where evidence indicates that a firm has profitably cut back the market's total output and raised price, the existence of monopoly power is clear. *United States v. Microsoft Corp*., 253 F.3d 34, 51 (D.C. Cir. 2001). Courts use two methods to

[16] Even the cases Sanofi cites confirm that coercion is the watchword. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015) ("Well-established case law makes clear that product redesign is anticompetitive when it *coerces* consumers and impedes competition.") (emphasis added); *id.* at 652 n.23 (collecting cases); *Mylan Pharms. Inc. v. Warner Chilcott Public Ltd. Co.*, 838 F.3d 421, 440 (3d Cir. 2016) (concluding that the product-hop claim asserted in that case was not viable but recognizing "the possibility that certain insignificant design or formula changes, *combined with other coercive conduct*, could present a closer call with respect to establishing liability in future cases.") (emphasis added).

assess monopoly power: (1) direct evidence of power to control prices and exclude competition, or (2) indirect evidence such as the defendant's share in the relevant market and the existence of barriers to entry. *Broadcom*, 501 F.3d at 307. Although these are alternative tests, Mylan has sufficiently alleged market power in *both* ways.

1. Mylan sufficiently alleged direct evidence of Sanofi's monopoly power.

To demonstrate direct evidence of Sanofi's monopoly power, Mylan may demonstrate that Sanofi profitably raised prices without causing competing firms to expand output and drive down prices. *See Broadcom*, 501 F.3d at 307. Sanofi's Lantus profits skyrocketed, and Sanofi sold Lantus at prices well in excess of marginal costs. *See* Compl. ¶ 216. From 2004–2019, Lantus generated $43.9 billion in U.S. net revenue. Drug Pricing Report at 28. During this time, Sanofi profitably raised prices (Compl. ¶ 19), and the market did not respond to such supracompetitive prices with increased output. In fact, Sanofi did not face any meaningful pricing constraints on Lantus or Toujeo.

The presence of Eli Lilly's Basaglar does not diminish Sanofi's monopoly power as alleged in Mylan's Complaint. *See* Compl. ¶¶ 212–222. Eli Lilly launched Basaglar in 2016 (D.I. 50 at 10), but Sanofi's insulin glargine prices continued to increase above competitive levels after this launch. *See* Compl. ¶ 19. And, in fact, Eli Lilly agreed to pay Sanofi royalties as part of the patent litigation settlement pertaining to Basaglar—Sanofi granted Eli Lilly a royalty-bearing license to sell Basaglar beginning in December 2016. *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 6 (1st Cir. 2020). Basaglar also never obtained a significant market share as compared to Sanofi's insulin glargine products. Insulin Report Documents at 32;[17] Eli Lilly Documents Produced with Insulin Report at 155; *see also Presque Isle Colon & Rectal*

[17] These documents are incorporated by reference in Mylan's Complaint. *See* Compl. ¶ 11, n.6.

Surgery v. Highmark Health, 391 F. Supp. 3d 485, 502 (W.D. Pa. 2019) (explaining that 65% market share was sufficient to plead monopoly power).

Sanofi also restricted market output by delaying FDA approval of Mylan's Semglee and minimizing market uptake once Semglee received FDA approval. *See* Compl. ¶¶ 4–17. Sanofi's ability to restrict the total market output by excluding Mylan's lower cost product is indicative of Sanofi's monopoly power. *Broadcom*, 501 F.3d at 307. Mylan did not secure any measurable sales until more than one year from market entry. *See* Compl ¶ 211. Such a stark deviation from a properly functioning generic market is a clear indication of Sanofi's monopoly power and demonstrates that Sanofi "broke the competitive mechanism." *Indivior Inc. v. Alvogen Pine Brook LLC*, 2023 WL 6936749, at *18 (D.N.J. July 10, 2023). That Sanofi was able to restrict generic market output while raising prices to supracompetitive levels is evidence of a textbook monopoly. *See* Compl. ¶ 19.

2. Mylan also alleged indirect evidence of monopoly power in the relevant market.

Monopoly power "may also be inferred from the structure and composition of the relevant market." *Broadcom*, 501 F.3d at 307. To support an inference of monopoly power, a plaintiff may plead that a firm has a dominant share in a relevant market, and that there were barriers to entry in the market. *FTC v. AbbVie Inc.*, 976 F.3d 327, 371 (3d Cir. 2020). "Barriers to entry are factors, such as regulatory requirements, high capital costs, or technological obstacles, that prevent new competition from entering a market in response to a monopolist's supracompetitive prices." *Broadcom*, 501 F.3d at 307.

Because Mylan alleged direct evidence of market power, it need not identify indirect evidence of monopoly power nor identify a relevant market. *See Broadcom*, 501 F.3d at 307 n.3. But, in any event, Mylan also sufficiently alleged indirect evidence of Sanofi's monopoly power.

a. Mylan identified the relevant market: injectable insulin glargine products.

The determination of a relevant product market is "highly factual" and best left to the trier of fact. *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 199 (3d Cir. 1992). Despite this well-settled precedent, Sanofi asks this Court to decide this highly factual issue on a motion to dismiss. Mylan alleges that the relevant market is injectable insulin glargine products, including Lantus, Toujeo, and Semglee. *See* Compl. ¶¶ 212–22.[18] Sanofi incorrectly argues that the relevant market is all basal insulin products. *See* D.I. 50 at 12. This is a factual dispute and, on a motion to dismiss, *Mylan's* allegations prevail. *See Fineman*, 980 F.2d at 199.[19] But even if the Court accepts Sanofi's invitation to weigh the facts—and it should not—Sanofi's arguments still fall short.

Sanofi leveraged its market share in the insulin glargine market from both Lantus and Toujeo to delay Semglee's FDA approval and diminish uptake once approved. *See* Compl. ¶¶ 4–17. Failure to consider these products as one market ignores the "commercial realities" of the market Sanofi created, that Mylan encountered upon entry, and that consumers faced. *Eastman*,

[18] *See also, e.g.*, *id.* ¶ 7 ("Any other Orange Book listing was improper and done with the specific intent to monopolize the market for injectable insulin glargine and prevent competition in violation of the Sherman Act and state laws."); *id.* ¶ 14 ("Sanofi did this not for any patient benefit or medical necessity, but to ensure that it prolonged its market power in the injectable insulin glargine market."); *id.* ¶ 17 ("Sanofi continues to offer steep rebates to payers only if they include all Sanofi injectable insulin glargine products on preferred tiers."); *id.* ¶ 21 ("Sanofi's monopolization of the injectable insulin glargine market and other related conduct has resulted in Sanofi facing lawsuits throughout the country alleging a variety of competition and unfair business practices violations in litigation brought by purchasers, payers, and at least six states and three counties."); *id.* ¶ 91 ("Over the years, the Orange Book identified Lantus as a single product made in two formulations: 'injectable' (i.e., the 'vial formulation,' which was initially sold 5 mL and 10 mL amounts), and 'injection' with an OptiClick injector pen (i.e., the 'cartridge formulation')."); *id.* ¶ 199 ("Sanofi recognized pushing the market to Toujeo as the only viable way to maintain its market power over injectable insulin glargine"); *id.* ¶ 209 ("In fiscal year 2020 Toujeo accounted for approximately 22% of Sanofi's injectable insulin glargine sales in the United States (measured by revenues, Sanofi does not report doses); this was easily enough to create a critical mass to force payers to remain loyal.").

[19] *See also, e.g.*, *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 326 (D.R.I. 2017) (relevant market is a "fact-intensive" issue "to be decided on a motion for summary judgment (if no genuine issue of material fact exists) or at trial"); *Indivior*, 2023 WL 6936749, at *15 n.25 ("[T]he determination of a relevant product market or submarket . . . is a highly factual one best allocated to the trier of fact.") (citations omitted).

504 U.S. at 482. In fact, it is common for courts considering the monopolization of pharmaceutical markets, with their unique regulatory attributes, to define the product market in this manner. *See New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 646–47 (2d Cir. 2015) (defining the market as the original brand product facing generic competition, the newly introduced brand product, and the generic foreclosed from the market).

"Competing products are in the same market if they are readily substitutable for one another; a market's outer boundaries are determined by the reasonable interchangeability of use between a product and its substitute, or by their cross-elasticity of demand." *Broadcom*, 501 F.3d at 307. Cross-elasticity measures "the extent to which consumers will change their consumption of one product in response to a price change in another," all else being equal. *Eastman*, 504 U.S. at 469 n.15. Two products that may appear to "compete" with each other to some degree, may not be part of the same antitrust market because they do not provide a price constraint. *See 3Shape Trios*, 2020 WL 2559777, at *10 (D. Del. May 20, 2020) (concluding that the complaint sufficiently alleged that dental aligners and metal braces were not in the same market), *R&R adopted*, 2020 WL 6938054 (D. Del. Nov. 25, 2020).

First, Sanofi argues that Mylan's market definition fails because it does not include additional insulin products, such as Levemir (insulin detemir), Tresiba (insulin degludec), Humalog Mix (insulin lispro), and Novolog Mix (insulin aspart). *See* D.I. 50 at 12–13. But these products have different active ingredients than Lantus, Toujeo, and Semglee (all insulin glargine). Sanofi is purposefully conflating therapeutic classes with relevant markets to hide its monopoly power despite clear market evidence that these products are not in the relevant market. These products did nothing to curb Sanofi's supracompetitive prices and provided no pricing constraint on Sanofi's Lantus or Toujeo. *See* Compl. ¶ 19; *Eastman*, 504 U.S. at 469–71. And

these products did not exhibit significant, positive cross-elasticity of demand with respect to Sanofi's insulin glargine products. *See* Compl. ¶ 219.

In short, not all basal insulin products belong in the relevant market, because not all basal insulin products have the same active ingredients, and PBMs do not include all of them on their formularies. *See* Insulin Rep. at 29. If a PBM chooses insulin glargine, that means it will likely choose to place Lantus on formulary, and accordingly Toujeo, given that the rebates for each product are tied, but *not* other basal insulins offered by ostensible competitors. *See* Compl. ¶ 203. Sanofi might disagree. *See* D.I. 50 at 12–13. But this dispute is not for this Court to decide on a motion to dismiss. *See Fineman*, 980 F.2d at 199.

Second, Sanofi claims that Mylan says nothing about Sanofi's dominance in the injectable insulin glargine market. *See* D.I. 50 at 14–15. But that is not true. Sanofi maintains a huge share of the *entire* basal insulin market and proclaims so in its documents. *See* Compl. ¶¶ 10, 18. In fact, Mylan's Complaint includes excerpts of Sanofi's internal documents produced to Congress that confirm Sanofi has the dominant share of the market for *all basal insulin*. *See id.* ¶ 10 ("Lantus is the **preferred** 1st **generation basal insulin**. We have succeeded at leveraging the size of Lantus to unlock preferred access for Toujeo."); *see also* Insulin Report Documents at 220. Thus, Mylan's indirect monopoly power allegations stand even if Sanofi's market definition were accepted over the one alleged in Mylan's Complaint.

b. Mylan also alleged barriers to entry protecting Sanofi's dominant share in the relevant market.

Sanofi next argues that Mylan's allegations about barriers to entry are conclusory. *See* D.I. 50 at 15 (citing Compl. ¶ 218). Not so. Mylan offered detailed allegations *throughout the Complaint* about the lengthy approval process to bring a pharmaceutical product to market. *See e.g.*, Compl. ¶¶ 43–44, 51–56, 68–79 (detailing regulatory hurdles for generic drug applications);

id. ¶ 76 (explaining that pursuing FDA approval through a paragraph IV certification results in a 30-month stay or less if the related patent litigation is resolved sooner); *see also, e.g.*, *id.* ¶ 128 (Mylan waiting for regulatory guidance from FDA regarding application process); *id.* ¶ 140–190 (Mylan's protracted legal battle with Sanofi regarding its 18 Orange Book listed patents). And FDA approval is not the end of the road for would-be generic competitors. In order to get to market, such competitors would require sufficient manufacturing facilities and ultimately will need to contract with PBMs to ensure formulary placement. *See id.*¶ 11, 15. Moreover, would-be generic competitors may also need to market the product to compete with Sanofi's marketing blitz regarding Toujeo. *See id.* ¶¶ 207. All these barriers to entry, which the Complaint adequately alleges, support Mylan's indirect evidence of monopoly power. *See AbbVie*, 976 F.3d at 372–73 (upholding the district court's finding of barriers to entry because a "generic drug has significant capital, technical, regulatory, and legal barriers to overcome."); *see also Sandoz, Inc. v. United Therapeutics, Corp.*, 2020 WL 697137, at *12 (D.N.J. Jan. 29, 2020) (same).

C. Sanofi's Anticompetitive Conduct Caused Antitrust Injury.

1. Sanofi's unlawful patent listings delayed Mylan's entry into the market.

Sanofi attempts to impose an artificially high causation requirement on Mylan, demanding that Mylan explain how Sanofi's improper Orange Book listings directly delayed Mylan's approval. *See* D.I. 50 at 16–21. But that is not the law. Antitrust causation only requires Mylan to show that Sanofi's antitrust violation was *a* material cause of Mylan's injury. *Suboxone*, 622 F. Supp. 3d at 78; *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 14 (1st Cir. 2020). "[D]ispositive weight should not be given to lists of possible alternative causes, which virtually any defendant can generate." Areeda & Hovenkamp ¶ 338a. "It is . . . enough that the antitrust violation contributes significantly to the plaintiff's injury, even if other factors amounted in the aggregate to a more substantial cause." *In re Lantus*, 950 F.3d at 14 (quoting

Areeda & Hovenkamp ¶ 338a); *Suboxone*, 622 F. Supp. 3d at 79; *Zenith Radio Corp. v. Hazeltine Rsch, Inc.*, 395 U.S. 100, 114 n.9 (1969). Antitrust suits are rarely dismissed on causation grounds.[20]

Despite these legal standards, Sanofi attempts to weave a causation story by inviting the court to take judicial notice of various "facts." *See* D.I. 50 at 16–21. And it relies on *In re Wellbutrin XL Antitrust Litigation*, 868 F.3d 132, 151–52 (3d Cir. 2017), an appeal from a *summary judgment* ruling, to support the argument that the Court can credit its version of events. *See* D.I. 50 at 17. This misreads *Wellbutrin*, which concluded that there was no genuine dispute of material fact that the 30-month stay would have continued to apply even if the defendant had not participated in the patent litigation. *See Wellbutrin*, 868 F.3d at 152–53. Here, there is no such agreement between the parties as to the impact of Sanofi's improper Orange Book listings and sham litigation, and there *are* factual disputes as to whether Mylan could have launched in the absence of those roadblocks. *See* Compl. ¶¶ 123–27.

Sanofi argues that, irrespective of its improper Orange Book listings, Mylan would not have applied for Semglee approval before 2017 because: (1) Mylan's desire to pursue a less expensive path for approval placed it in a regulatory dead zone, D.I. 50 at 17–18; and (2) Mylan's Semglee allegedly had issues, including a need for additional data, *id.* at 19–20. Sanofi also argues that the 30-month stay resulting from Sanofi's Orange Book patents did not impede Semglee's approval because FDA never granted tentative approval for Semglee during

[20] Notably, an antitrust plaintiff need not allege material causation separately for each component of the alleged scheme; rather, the injuries inflicted by the defendant's allegedly anticompetitive activities should, instead, be viewed as a whole. *See Suboxone*, 622 F. Supp. 3d at 78. Further, whether conduct constitutes intervening conduct that breaks the chain of causation in an antitrust action and whether intervening conduct is a foreseeable consequence of a defendant's actions are questions of fact to be submitted to the jury. *Id.* So long as "the plaintiff's claim of causation is plausible, it should not be dismissed summarily merely because alternative causation stories are plausible as well." Areeda & Hovenkamp ¶ 338a.

the stay. *Id.* at 18. Sanofi next asserts that these fact-based arguments are supported by judicially noticeable documents, which Sanofi encourages the Court to review and use for drawing inferences in Sanofi's favor. *Id.* at 19. None of these arguments is proper on a motion to dismiss. Although a court may take judicial notice of the "existence" of a document, it may not make a judgment about "the truth of the facts recited therein," let alone draw inferences in the movant's favor on a motion to dismiss. *Doe v. Princeton Univ.*, 30 F.4th 335, 342 (3d Cir. 2022) (quotation omitted); *see also Dunn v. PHH Mortg. Corp.*, 2021 WL 870659, at *3 (D.N.J. Mar. 9, 2021) (judicially noticing documents for their truth would authorize trial by public documents). The Court should reject Sanofi's invitation to draw inferences and make credibility determinations that judicial notice will not permit.

Mylan alleged that it could and would have immediately sought FDA approval for Semglee had Sanofi not improperly listed a thicket of sham patents in the Orange Book. *See* Compl. ¶¶ 126–27. Once Sanofi listed those sham patents, Mylan knew any such application would necessarily be delayed by a 30-month stay (*see id.* ¶ 127), during which time FDA might come to a different conclusion about whether Semglee should be classified as a "generic" or "biologic" due to the passage of a new law—an outcome that would have voided Mylan's application. *See id.* ¶ 128; *see also supra* 2, n.33 above. Given the unavoidable timing roadblocks that Sanofi erected in Mylan's regulatory path, Mylan was forced to wait for FDA to weigh in on whether it should take the generic or biosimilar approval path. *See id.* ¶¶ 128–39. But, and this is critical, Mylan's engagement with FDA for regulatory approval was artificially prolonged *because* Sanofi foreclosed the possibility of expedited final approval by improperly listing numerous invalid patents in the Orange Book. *See id.* Sanofi disputes these allegations, but this factual dispute is not properly resolved on a motion to dismiss. *See Doe*, 30 F.4th at 342.

2. Sanofi's exclusive dealing foreclosed Mylan from the market.

Sanofi argues that Mylan failed to allege market foreclosure. D.I. 50 at 9–10. Not so. Mylan alleged that it did not make *any* measurable sales until 2021. Compl. ¶ 211. And, in any event, even if Mylan did not allege complete market foreclosure, that is not the standard. *See Indivior*, 2023 WL 6936749, at *17.

Mylan's burden is only to show harm to competition, which can be established either through direct evidence or indirect evidence. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). Direct evidence can come in the form of "reduced output, increased prices, or decreased quality." *Id.* Indirect evidence can include the extent to which the market is foreclosed as a "proxy for anticompetitive harm." *McWane, Inc. v. FTC*, 783 F.3d 814, 835 (11th Cir. 2015).

While a plaintiff may rely on foreclosure as a proxy for competitive harm, it need not "place an exact number on the percentage foreclosed." *McWane*, 783 F.3d at 838. The plaintiff can always rely on qualitative evidence, *e.g.*, that the exclusive arrangement "tied up the key dealers" in the market. *Id.* Even when a plaintiff eventually relies on a numerical figure, its complaint need not include a specific number. *See FTC v. Qualcomm Inc.*, 2017 WL 2774406, at *24 (N.D. Cal. Jun. 26, 2017). After all, a complaint must offer facts demonstrating a legal wrong, not "mathematical precision." *Landers v. Quality Commc'ns, Inc.*, 771 F.3d 638, 646 (9th Cir. 2015) (as amended). To plead a foreclosure percentage, a plaintiff would need to know the defendant's sales figures and contract terms, which plaintiffs cannot access without discovery. *See E. I. du Pont de Nemours & Co. v. Kolon Indus.*, 637 F.3d 435, 452 n.12 (4th Cir. 2011). Furthermore, whether an exclusive dealing arrangement forecloses a sufficient share of the market to adversely affect competition "implicate[s] factual disputes that cannot be resolved at [the motion to dismiss] stage." *Regeneron Pharms., Inc. v. Amgen Inc.* 2023 WL 1927544, at

*6 (D. Del. Feb. 10, 2023), *R&R adopted*, 2023 WL 2587809 (D. Del. Mar. 21, 2023).[21]

Sanofi points to Eli Lilly and Novo Nordisk's entry into *a* market as proof there was no foreclosure. *See* D.I. 50 at 10. Whether and how Sanofi's conduct impacted Novo Nordisk is immaterial, because it is not in the relevant market. *See*, *supra* at 23–26. And, in any event, even according to *Sanofi*, Sanofi captured huge swaths of the basal insulin market as a whole. *See* Compl. ¶ 10 (boasting of "76% Coverage in Commercial and 74% in Medicare"); *see also* Insulin Report Documents at 220. Further, Sanofi, Eli Lilly, and Novo Nordisk are alleged co-conspirators in a conspiracy to keep the price of insulin high. *See*, *e.g.*, Second Am. Compl. ¶ 1, *In re: Direct Purchaser Insulin Pricing Litigation*, No. 3:20-cv-3462 (D.N.J. Nov. 8, 2022), D.I. 261. At a minimum, Mylan is entitled to discovery as to how Sanofi targeted Mylan compared to brand manufacturers like Eli Lilly and Novo Nordisk.

Finally, the question is not whether Mylan and other competitors were able to obtain sales but whether Mylan would have obtained more sales but for Sanofi's conduct. "The fact that generics gained market share and competed for some number of payor contracts does not dispel the genuine issues of material fact as to whether the probable effect of [Sanofi]'s conduct would have been to 'substantially lessen competition, rather than merely disadvantage rivals.'" *Indivior*, 2023 WL 6936749, at *18 (quoting *Eisai*, 821 F.3d at 403).

II. Mylan's Additional Claims Succeed for Similar Reasons Already Identified.

A. Mylan's Attempted Monopolization, Exclusive Dealing, and Violation of the New Jersey Antitrust Law Claims Survive.

Mylan has succeeded in establishing a claim for attempted monopolization. To plead attempted monopolization, Mylan must sufficiently allege "(1) that the defendant has engaged in

[21] *See also Regeneron*, 2023 WL 2587809, at *1 ("[F]oreclosure [is an] issue [that] is not all that suitable for a motion to dismiss."); *Indivior*, 2023 WL 6936749, at *17) (foreclosure is a factual issue).

predatory or anticompetitive conduct with (2) specific intent to monopolize and (3) a dangerous probability of achieving monopoly power." *Presque Isle Colon & Rectal Surgery v. Highmark Health*, 391 F. Supp. 3d 485, 502 (W.D. Pa. 2019) (citation omitted). Sanofi's arguments seeking dismissal of this claim fail for the same reasons previously stated. *See supra* pp. 1–30. Sanofi not only had a "dangerous probability of achieving monopoly power," it, in fact, *did have monopoly power*. *See supra* pp. 20–26. Moreover, determining this question is a "fact-sensitive inquiry" that courts typically should not resolve at the pleading stage. *Broadcom*, 501 F.3d 297, at 319.

Sanofi's arguments that Mylan has not pleaded specific intent (D.I. 50 at 25) ignore the numerous references in Mylan's Complaint to damning statements in *Sanofi's* internal documents declaring anticompetitive intent. *See, e.g.*, Compl. ¶ 14 ("Establish Toujeo and convert the franchise"); *id*. ¶ 199 (Sanofi wanted to "maximize the glargine family and defend our leadership position" before biologic follow on entry); *id.* ¶¶ 9, 14 ("[Toujeo] [l]aunch plan includes key tactics . . . and necessary investment to ensure switch before biologic follow on entry.").

Finally, Mylan's exclusive dealing claims, New Jersey Antitrust Act claims, and Section 3 of the Clayton Act claims survive for the same reasons Mylan's Sherman Act Section 2 claims survive. *Eisai*, 821 F.3d at 402 n.11.

B. Mylan's Claims of Tortious Inducement of Refusal to Deal Survive.

Sanofi argues that Mylan's allegations fail because Mylan does not allege any prospective contractual relationships with any particularity (D.I. 50 at 26), but Mylan need only identify a "prospective contractual relationship," which is "something less than a contractual right, something more than a mere hope." *Thompson Coal Co. v. Pike Coal Co.*, 488 Pa. 198, 209 (1979); *see also Sandoz Inc. v. Lannett Co*., 544 F. Supp. 3d 505, 511–12 (E.D. Pa. 2021)

(quoting *Thompson*, 488 Pa. at 209). The standard is objective, and whether a party's expectation is reasonable "generally involves questions of fact." *Sandoz*, 544 F. Supp. 3d at 512. Thus, whether Mylan's contracting expectations were reasonable is not appropriately decided on a motion to dismiss.

Additionally, the Complaint sufficiently identifies relationships through which contracts would ordinarily arise, identifying the likely contracting parties and how Sanofi excluded Mylan from these contracts. *Sandoz*, 544 F. Supp. 3d at 512. In fact, Mylan explains that "[b]ecause of Sanofi's conduct, payers were induced into not dealing with Mylan and instead remaining beholden to Sanofi's larger insulin franchise." Compl. ¶ 260. Mylan also alleges that, through this switch, Sanofi steered patients away from the imminently genericized Lantus (i.e., Mylan's potential customers) to Toujeo. *Id.* ¶ 3. Mylan specifically alleges that having Lantus and Toujeo tied together resulted in "Mylan's less expensive biosimilar" being "effectively excluded from commercial and noncommercial formularies and out of the reach of patients." *Id.* ¶ 15. Indeed, when Semglee launched in the Fall of 2020, "payers were unwilling to entertain a switch away from Lantus because the prospect of then having to pay more for Toujeo was crippling." *Id.* ¶ 210. These allegations are sufficient.

III. Mylan's Complaint Provides Each Sanofi Entity with Sufficient Notice of the Claims Levied Against It.

Sanofi argues that Mylan has failed to specifically describe how each defendant entity participated in the alleged conduct. *See* D.I. 50 at 27–28. But a complaint need not contain detailed defendant-by-defendant allegations. *In re Processed Egg Prods. Antitrust Litig.*, 821 F. Supp. 2d 709, 719 (E.D. Pa. 2011). Rather, defendants "must have reasonable, not exhaustive, notice of the allegations." *Id.* at 719. So long as the allegations in the complaint are sufficient to put the defendants on notice of the charges against them the complaint passes muster under Rule

8 of the Federal Rules of Civil Procedure ("Rule 8"). *Hotaling & Co., LLC v. Berry Sols. Inc.*, 2021 WL 4860096, at *7 (D.N.J. Oct. 19, 2021).

Nothing in Rule 8 prohibits collectively referring to multiple defendants where the complaint alerts defendants that identical claims are asserted against each. *Hotaling*, 2021 WL 4860096, at *7; *see also Big Dog Energy, LLC v. Primeblock Operations LLC*, 2023 WL 3645960, at *5 (W.D. Pa. May 25, 2023). This is especially true where, as here, the individual Sanofi defendants are related corporate entities and in privity with one another. *See JD Glob. Sales, Inc. v. Jem D Int'l Partners, LP*, 2023 WL 4558885, at *8 (D.N.J. July 17, 2023).

Mylan's allegations are far from the type of group pleadings at issue in the cases Sanofi cites or what Rule 8 intends to prevent.[22] Mylan identifies with specificity the relevant patent litigation and Orange Book listings. Compl. ¶¶ 114–122; 145. And Mylan goes into painstaking detail regarding the demise of Sanofi's Orange Book patents. *Id.* ¶¶ 140–190. Mylan also cites Sanofi's internal documents produced to Congress to show that Sanofi introduced and maneuvered Toujeo to entrench its market dominance. *Id.* ¶ 199. There is nothing unclear or vague as to Mylan's allegations, and Mylan is not privy to the details of Sanofi's internal corporate structure. *See id.* ¶ 33 n.13 (referencing Sanofi's "lists of hundreds of subsidiaries and affiliates"). Discovery will reveal the specific roles of each Sanofi entity. *See Ioengine, LLC v.*

[22] Sanofi relies on inapposite fraud and section 1983 cases involving large groups of unconnected defendants. *See Campbell v. City of New Brunswick*, 2018 WL 2234899, at *2 (D.N.J. May 16, 2018) (false arrest lawsuit); *Grande v. Starbucks Corp.*, 2019 WL 1455445, at *1 (E.D. Pa. Apr. 2, 2019) (customer complaint alleging twelve Starbucks employees "fraudulently promis[ed] stores would be safe and clean when in fact the stores were dirty"); *Hynson ex rel. Hynson v. City of Chester, Legal Dep't*, 864 F.2d 1026, 1026–27 (3d Cir. 1998) (Section 1983 lawsuit); *Caristo v. Blairsville-Saltsburg Sch. Dist.*, 370 F. Supp. 3d 554, 558 (W.D. Pa. 2019) (same); *Bartol v. Barrowclough*, 251 F. Supp. 3d 855, 856 (E.D. Pa. 2017) (same). The other cases Sanofi cites are similarly far afield from Mylan's Complaint. *See e.g., Ezekwo v. Jacobs*, 2023 WL 3848332, at *1 (D.N.J. Jun. 6, 2023) (plaintiff was a "frequent filer" who "routinely and frequently submits filings that are unintelligible, duplicative, and aggressive"), *appeal filed* (July 7, 2023); *Mensah v. Manning*, 2020 WL 91089, at *6–7 (D.N.J. Jan. 8, 2020) (plaintiff on notice for previous dismissal under Rule 8 and subsequent complaint bringing claims against seven corporate defendants was only fourteen pages long).

PayPal Holdings, Inc., 2019 WL 330515, at *11 (D. Del. Jan. 25, 2019).

IV. This Court Has Personal Jurisdiction Over Sanofi S.A.

This Court's exercise of specific jurisdiction over Sanofi S.A. is proper. The relevant inquiry is whether a defendant has sufficient contacts with the ***United States***. *See In re Auto. Refinishing Paint Antitrust Litig.*, 2002 WL 31261330, at *6 (E.D. Pa. July 31, 2002) (hereinafter "*Auto Refinishing*"), *aff'd*, 358 F.3d 288 (3d Cir. 2004). As detailed in the appended declaration, Sanofi S.A. has purposefully directed numerous activities towards the United States relating to its monopolistic scheme. *See* Mills Decl. ¶¶ 4–12. Specific jurisdiction exists here. *See In re NBR Antitrust Litig.*, 2005 WL 8179729, at *1 (W.D. Pa. July 5, 2005), *R&R adopted*, 2005 WL 8179728 (W.D. Pa. Aug. 24, 2005).

Perhaps the most striking example of this Court's proper exercise of personal jurisdiction over Sanofi S.A. is the latter's efforts in the U.S. to keep Lantus on preferred formulary placement. *See* Mills Decl. ¶ 9. Sanofi has engaged in significant additional conduct in the United States concerning its scheme. To begin, on February 25, 2015 Sanofi announced that FDA approved Toujeo and expressly stated its intent to direct activities towards the United States, noting that "Toujeo is expected to be available in the U.S. at the beginning of Q2 2015." *See* Mills Decl. ¶ 6. Though Sanofi failed to indicate which entity issued the press release, the announcement was tellingly made from Paris—the principal place of business of Sanofi S.A. *See id.*; Compl. ¶ 27. On June 4, 2015, Sanofi announced—from Paris—clinical trials for Toujeo intended to evaluate Toujeo's effects on people in the United States. *See* Mills Decl. ¶ 7. Likewise, Sanofi issued a September 28, 2015 press release—again from Paris—discussing its settlement with U.S-headquartered Eli Lilly concerning Lantus patents. *See id.* ¶ 8. And on December 4, 2017, Sanofi—from Paris—issued a press release to the "USNewswire" touting Toujeo's clinical success. *See* Mills Decl. ¶ 10.

Moreover, Sanofi S.A. frequently testifies before Congress regarding conduct pertaining to its insulin glargine products in the *United States*. For example, on April 10, 2019, Kathleen W. Tregoning—Executive Vice President of Sanofi and based out of Paris—testified before Congress concerning issues related to pricing and affordability of insulin in the U.S., including Lantus and Toujeo. *See id.* ¶ 11. Further, just recently, Sanofi S.A. CEO, Paul Hudson, testified before the Senate Committee on Health, Education, Labor & Pensions, once again pertaining to affordable insulin access in the United States. *See id*. ¶ 12.

Together, these events demonstrate Sanofi's purposeful activity directed towards the United States as they relate to Sanofi's efforts to monopolize the insulin glargine market and significant financial interest in protecting its profit base. Sanofi S.A. is, thus, subject to the jurisdiction of this Court. *See* 35 U.S.C. § 293; *see also Auto Refinishing*, 2002 WL 31261330, at *9. At a minimum, this Court should permit jurisdictional discovery into Sanofi S.A.'s contacts. *See Auto Refinishing*, 358 F.3d at 291–92; *see also Toys "R" Us, Inc. v. Step Two, S.A.*, 318 F.3d 446, 456 (3d Cir. 2003); *In re Diisocyanates Antitrust Litig.*, 2020 WL 1140245, at *7 (W.D. Pa. Mar. 9, 2020). Denying a request for jurisdictional discovery is appropriate only when the claim at issue is "'clearly frivolous.'" *Toys "R" Us, Inc.*, 318 F.3d at 456 (citation omitted)). Here, it is not.

CONCLUSION

For all of these reasons, Sanofi's Motion to Dismiss must be denied.

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Respectfully submitted,

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